Illegal clinical trial by GVK Bio-Science

948. SHRI UDAY PRATAP SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that M/s GVK Bio-Science was doing illegal clinical trials for M/s Glenmark and Ranbaxy and US Multi National Company, Pfizer as recently reported in media; and

(b) if so, the details of the case and what action has been taken by DCGI in this matter?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) The news reports in May, 2004, alleging conduct of illegal clinical trial by M/s GVK Bio-Science Hyderabad, were investigated by State Drug Control Authorities, Andhra Pradesh and sub-zonal office of Central Drugs Standard Control Organization (CDSCO) at Hyderabad.

As per investigation report, M/s GVK Bio-Sciences Hyderabad, had not undertaken clincial trials, for which prior permission is required. The firm had conducted bio-equivalence study in March-April, 2004, for M/s. Glenmark Pharma for their formulation Oxybutine Hydrocloride, M/s. Ranbaxy Laboratories Ltd., Gurgaon for their formulations Azithromycin and Clarithromycin. The studies had been undertaken after due approval obtained from institutional Ethics Committee. The drugs in question are approved and well established in the country.

Current population of India

949. SHRI MANOJ BHATTACHARYA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state;

(a) the present population of the country as on April, 2004 together with the present birth rate;

(b) whether the various schemes launched so far to stabilize the country's population have yielded any positive results and if so, the details thereof; and

(c) If not, steps propsoed to be taken in this direction to encourage small family norms in the country?